

**Premarket Notification
510(k) Summary of Safety and Effectiveness
[As Required by 21 CFR 807.92(a)]**

Date prepared: August 27, 2003

1. Submitter & Manufacturing Site: Belmont Instrument Corporation
780 Boston Road
Billerica, MA 01821

Establishment Registration Number: 1219702
2. Contact Person: Uraivan P. Labadini, Quality Assurance/Regulatory Affairs Manager

Telephone: (508) 663-0212 Ext. 28 Fax: (508) 663-0214
3. Trade Name: The Belmont Fluid Management System, *FMS2000*
4. Common name: Infusion Pump with Warmer.
5. Classification name: Infusion Pump (per 21 CFR section 880.5725)
6. Product Code: 80 FRN Infusion Pump
Device Class: Class II
7. Performance Standards:
No performance standards have been officially adopted by the F.D.A.
8. The Modified Belmont Fluid Management System, *FMS2000*, is substantially equivalent to the Belmont Fluid Management System, *FMS2000*, which was the subject of Premarket Notification #K972284 submitted in June, 1997.

9. Brief Description: The Belmont Fluid Management System, *FMS2000*, combines advanced microprocessor technology with an efficient mechanical system to provide a high speed, simple and safe system for rapid infusion of warmed fluid. The Belmont *FMS2000* infuses blood, replacement IV fluids or irrigation fluids warmed to physiologic temperature at user-set rates from 10 to 750 milliliters per minute (ml/min). A low infusion rate at 2.5 ml/min (150 ml/hr) is also available without heating.

The system monitors temperature, line pressure, and air in the fluid path to ensure safe operation and alarms at all unsafe conditions. A hardware override circuit prevents unsafe operation in case of system computer failure. A touch screen displays flow rate, total fluid infused, temperature, line pressure, alarm and status messages and proper procedures to proceed safely after an alarm situation.

A battery backup allows for mobile transport of the patient and system. During battery operation, fluid warming is disabled while pump operation and safety monitoring remain active.

10. Intended Use

The Belmont *FMS2000* is for use in high blood loss surgical procedures, trauma and any situation where rapid replacement of warmed blood or replacement fluid at 10 -750 ml/min is required. It can also be used to deliver irrigation fluids at rates up to 750 ml/min.

11. Summary of the technological characteristics of the modified Belmont *FMS2000* compared to the current Belmont *FMS2000*.

There are no changes to the operating principle, energy type, environmental specifications, or performance specifications. There are no changes to the Belmont *FMS2000* hardware, changes in software only.

12. Summary of Nonclinical Tests and Results

In order to verify performance of the Belmont *FMS2000* in support of substantial equivalence, the following tests were carried out:

- a. The ability of the system to pump fluids accurately over the full range of flow rate and operating conditions including different input fluid temperatures, different back pressure, change in ambient temperature, and change in fluid viscosity.
- b. The ability of the system to warm cold fluids to physiological temperature over the full range of flow rate and operating conditions.

- c. The ability of the system to detect and alarm at unsafe or ineffective operating conditions including operator errors, the failure of the system sensors, and other internal system malfunctions.

The Belmont *FMS2000* performed within specification in all of the above tests.

The system was tested for hemocompatibility by testing for red cell hemolysis, and red cell fragility. The system was found to have negligible effect on anticoagulated blood. Hemolysis assessment was done using 'Sigma Diagnostics, Plasma Hemoglobin' Procedure No. 527.

- 13. Conclusion: The Modified Belmont *FMS2000* is substantially equivalent to the Belmont Fluid Management System , *FMS2000*, which was the subject of Premarket Notification #K972284 and received 510(k) approval in November 1997.



SEP 16 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Uraiwan P. Labadini
Quality Assurance Regulatory Affairs Manager
Belmont Instrument Corporation
780 Boston Road
Billerica, Massachusetts 01821

Re: K032674

Trade/Device Name: The Belmont Fluid Management System (FMS₂₀₀₀)
Regulation Number: None
Regulation Name: Thermal Infusion Fluid Warmer
Regulatory Class: Unclassified
Product Code: LGZ
Dated: August 27, 2003
Received: September 3, 2003

Dear Ms. Labadini:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink that reads "Susan Runner". The signature is written in a cursive, flowing style.

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

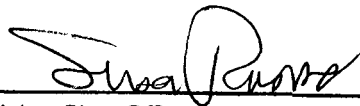
510(k) number: K032674Device Name: Belmont Fluid Management System (*FMS2000*)

Indications For Use:

- A. Infusion of crystalloid, colloid, or blood product, including packed red blood cells, as volume replacement for patients suffering from blood loss due to trauma or surgery.
- B. Infusion of warmed fluid to rewarm patients after surgery or for hypothermia.
- C. Infusion of warmed fluid for irrigation in urology procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices510(k) Number: K032674Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐